

PATENT Attorney Docket No. STK-008CN (7557/16)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Oppermann et al.

SERIAL NO.: 09/754,831 GROUP NO.: 1647

FILING DATE: January 3, 2001 EXAMINER: Not Yet Assigned RECEIVED

TITLE: OSTEOGENIC DEVICES

Commissioner for Patents FEB 1 3 2003

Washington, D.C. 20231 TECH CENTER 1600/2900

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Each of the listed documents was either previously cited by the Examiner or submitted for consideration in the application from which this application claims priority under 35 U.S.C. § 120, namely, USSN 08/375,901. Accordingly, pursuant to 37 C.F.R. § 1.98(d), Applicants have not supplied copies of the documents listed on the attached Form PTO-1449, but shall do so upon request.

### **REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed:

X	(1)	within three (3) months of the <b>filing date</b> of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months
		of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an
		international application, or before the mailing of the first Office action on the
		merits, or before the mailing of a first Office action after the filing of a request for
		continued examination under 37 C.F.R. 1.114; or
	(2)	after the period defined in (1) but before the mailing date of a <b>final action</b> or a <b>notice</b> of allowance under 37 C.F.R. 1.311, and
		the requisite Statement is below, OR

Information Disclosure Statement Serial No. 09/754,831 Page 2 of 2

		the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or
	(3)	after the mailing date of a <b>final action</b> or <b>notice of allowance</b> but before the payment of the <b>issue fee</b> , <b>AND</b>
		the requisite Statement is below, AND
		the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.
PTC	-	fully requested that each of the patents and publications listed on the attached Form ther information contained herein, be made of record in this application.
		STATEMENT
	As required	under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that
	1	Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application <b>not more than three months</b> prior to the filing of the Information Disclosure Statement; or
	2	No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Date: February 5, 2003 Reg. No.: 41,418

Tel. No.: (617) 248-7240 Fax No.: (617) 248-7100

2566036-1

Respectfully submitted,

Patrick R. H. Waller, Ph.D. Attorney for Applicants

Testa, Hurwitz, & Thibeault, LLP

High Street Tower 125 High Street

Boston, Massachusetts 02110



FORM PTO - 1449

# INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: STK-008CN

APPLICANT: Oppermann et al.

SERIAL NO.: 09/754,831

FILING DATE: 1/3/01 GROUP: 1647

T	т	0	D		TICK	TT	DOOLD	ATENTED
ι	J.	5.	Τ.	А	LI EF	4 I	DUCU	MENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME		CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	4,294,753	10/13/81	Urist		530	395	
	A2	4,394,370	7/19/83	Jefferies		424	15	
	A3	4,434,094	2/28/84	Seyedin et	al.	530	416	
	A4	4,455,256	6/19/84	Urist		530	350	
	A5	4,563,350	1/7/86	Nathan et a	al.	424	95	
	A6	4,563,489	1/7/86	Urist		524	21	
	A7	4,774,322	9/27/88	Seyedin et	al.	530	353	
	A8	4,795,804	1/3/89	Urist	·	530	350	
	A9	4,804,744	2/14/89	Sen		530	350	OFN/E
	A10	4,810,691	3/7/89	Seyedin et	al.	514	2	RECEIVE
· - ·	A11	8,843,063	6/27/89	Seyedin et	al.	514	2	FEB 1 3 200
	A12	4,877,864	10/31/89	Wang et al	•	530	324 T	ECH CENTER 16
	A13	5,013,649	5/7/91	Wang et al		435	69.1	CON CENTER TO
	A14	5,106,626	4/21/92	Parsons et	al.	424	423	
	A15	5,106,748	4/21/92	Wozney et	al.	435	252.3	
	A16	5,108,922	4/28/92	Wang et al	•	435	240	
	A17	5,116,738	5/26/92	Wang et al		435	69.1	
	A18	5,141,905	8/25/92	Rosen et al	l <b>.</b>	435	69.1	
-	A19	5,154,931	10/13/92	Kruger et a	ıl.			
	A20	5,166,058	11/24/92	Wang et al		435	69.1	
	A21	5,187,076	2/16/93	Wozney et	al.	435	69.1	
_	A22	5,250,302	10/5/93	Opperman	et al.	424	422	
	A23	5,366,875	11/22/94	Wozney et	al.			
	A24	5,585,237	12/17/96	Opperman	n et al.	435	6	
EXAMI	VER		1		DATE CONS	SIDERED	<u> </u>	

Sheet 2 of 4 FORM PTO - 1449 ATTORNEY DOCKET NO.: STK-008CN NFORMATION DISCLOSURE STATEMENT APPLICANT: Oppermann et al. SERIAL NO.: 09/754,831 FILING DATE: 1/3/01 GROUP: 1647 FOREIGN PATENT DOCUMENTS DOCUMENT DATE COUNTRY **CLASS** ABSTRACT **ENGLISH** EXAM. SUB FILING INIT. NUMBER CODE **CLASS** DATE ONLY LANG (Y/N) **B**1 12/5/85 85/05274 PCT B2 1/30/86 86/00526 **PCT B**3 88/00205 1/14/88 **PCT** B4 89/09605 10/19/89 PCT **B5** 89/10409 11/2/89 **PCT B6** 90/03733 4/19/90 **PCT B7** 90/11366 10/4/90 PCT **B8** 91/02744 3/7/91 **PCT B9** 93/00049 1/7/93 PCT TECH CENTER 1600/2900 B10 0128041 12/12/84 EP B11 0148155 7/10/85 EP B12 0169016 1/22/86 EP B13 0182483 5/28/86 EP **B14** 0212474 3/4/87 OTHER ART, JOURNAL ARTICLES, ETC. EXAM. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) INIT. CI Canalis et al., "Stimulation of DNA and Collagen Synthesis by Antologous Growth Factor in Cultured Fetal Rat Calvaria," Science 210:1021-1023 (1980). C2 Centrella, "Transforming and Nontransforming Growth Factors are Present in Medium Conditioned by Fetal Rat Calvariae," Proc. Natl. Acad. Sci. USA 82:7335-7339 (1985). C3 Colowick et al., Methods in Enzymology 146:294-312 (1987).

Farley et al., "Human Skeletal Growth Factor: Characterization of Mitogenic Effect on Bone Cells In

Glowacki et al., "Application of the Biological Principle of Induced Osteogenesis for Craniofacial Defects,"

**DATE CONSIDERED** 

C4

C5

**EXAMINER** 

Vitro," Biochem. 21:3508-3513 (1982).

Lancet 1:959-963 (1981).

<b>FORM</b>	PTO	- 1449
-------------	-----	--------

FEB 1 D 2003

ATTORNEY DOCKET NO.: STK-008CN

PINFORMATION DISCLOSURE STATEMENT

APPLICANT: Oppermann et al.

RECEIVED

SERIAL NO.: 09/754,831

FEB 1 3 2003 GROUP: 1647

FILING DATE: 1/3/01

TECH CENTER 1600/2900

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER ART, JOURNAL ARTICLES, ETC.  OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)						
	C6 Klausner, "Collagen Corp. Isolates Cartilage Inducers," <u>Biotechnology</u> 3:567-568 (1985).						
	C7	LeGendre et al., "Direct Protein Microsequencing from Immobilon-P Transfer Membrane," <u>Biotechniques</u> 6:154-159 (1988).					
	C8	Lyons et al., "Vgr-1, A Mammalian Gene Related to Zenopus Vg-1, Is A Member of the Transforming Growth Factor B Gene Superfamily," <u>Proc. Natl. Acad. Sci. USA</u> 86:4554-4558 (1989).					
	C9	Maugh, "Human Skeletal Growth Factor Isolated," Science 217:819 (1982).					
	C10	Olson et al., "Deglycosylation of Chondroitin Sulfate Proteoglycan by Hydrogen Fluoride in Pyridine," Analyt. Biochem. 146:232-257 (1985).					
	C11	Padgett et al., "A Transcript From A Drosophila Pattern Gene Predicts A Protein Homologous To The Transforming Growth Factor-B Family," Nature 325:81-84 (1987).					
	C12	Reddi, "Cell Biology and Biochemistry of Endochondral Bone Development," Collage Rel. Res. 1:209-226 (1981).					
	C13	Reddi, "Implant-Stimulated Interface Reactions During Collagens Bone Matrix-Induced Bone Formation," Journal of Biomedical Materials Research 19:233-239 (1985).					
	C14	Rosen et al., "Purification and Molecular Cloning of a Novel Group of BMPs", <u>Connect. Tissue Res.</u> 20:313-319 (1989).					
	C15	Rudinger, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," Peptide Hormones (Parsons, et al. ed.), University Park Press, Baltimore, 1-7 (1976).					
	C16	Sampath et al., "Dissociative Extraction and Reconstitution of Extracellular Matrix Components Involved in Local Bone Differentiation," <a href="Proc. Natl. Acad. Sci. USA">Proc. Natl. Acad. Sci. USA</a> 78:7599-7603 (1981).					
	C17	Sampath et al., "Drosophila Transforming Growth Factor β Superfamily Proteins," Proc. Natl. Acad. Sci. USA 90:6004-6008 (July 1993).					
	C18	Sampath et al., "Isolation of Osteogenin, An Extracellular Matrix-Associated, Bone-Inductive Protein, by Heparin Affinity Chromatography," <a href="Protein">Proc. Natl. Acad. Sci. USA</a> 84:7109-7113 (1987).					
	C19	Sampath et al., "Role of Extracellular Matrix Components in Cartilage and Bone Induction," <a href="Extracellular Matrix: Structure"><u>Extracellular Matrix: Structure and Function (A.H. Reddi Ec.) Allen R. Liss, Publ., NY</u> 412-428 (1985).</a>					
	C20	Sampath et al., "Homology of Bone-Inductive Proteins from Human, Monkey, Bovine, and Extracellular Matrix," Proc. Natl. Acad. Sci. USA, 80:6591-6595 (1983).					
	C21	Seyedin et al, "In Vitro Induction of Cartilage-Specific Macromolecules by a Bone Extraci," Proc. Natl. Acad. Sci. USA 82:2267-2271 (1985).					
EXAMIN	ER	DATE CONSIDERED					

FEB 10 2003

FQRM PTO - 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: STK-008CN

APPLICANT: Oppermann et al.

SERIAL NO.: 09/754,831

FILING DATE: 1/3/01

GROUP: 1647

	1.					
	OTHER ART, JOURNA	L ARTICLES, ETC.				
EXAM. OTHE						
C22	Seyedin et al., "Purification and Characterization Demineralized Bone," J. Cell Biol. 97:1950-1	ion of Two Cartilage-Inducing Factors from Bovine 953 (1983).				
C23	Simpson, "Growth Factors Which Affect Bone					
C24	Urist et al., "B-tricalcium Phosphate Delivery Res. 187:277-280 (1984).	System for Bone Morphogenetic Protein," Clin. Orth. Rel.				
C25	C25 Urist et al., "Human Bone Morphogenic Protein (hBMP)," Proc. Soc. Exp. Bio. Med. 173:194-199 (1983).					
C26	Urist et al., "Purification of Bovine Bone Morphogenetic Protein by Hydroxyapatite Chromatography," <u>Proc. Natl. Acad. Sci. USA</u> 81:371-375 (1984).					
C27	Int. (Suppl) Ab No. 146, ppA37 (1988).  Wang et al., "Purification and Characterization of Other Distinct Bone-Inducing Factors," Proc. Natl. Acad. Sci. USA 85:9484-9488 (1988).					
C28						
C29						
C30	C30 Weeks et al., "A Maternal mRNA Localized to the Vegetal Hemisphere in Xenpus Eggs Codes For A Growth Factor Related to TGF-B," Cell 51:861-867 (1987).					
C31	C31 Wozney et al., "Identification Through Molecular Cloning of Factors Involved in Vivo Cartilage Formation," Calcified Tissue Int. (Suppl.) Ab No. 147, A37 (1988).  C32 Wozney et al., "Novel Regulators of Bone Formation: Molecular Clones & Activities," Science 242:1528-1534 (1988).					
C32						
EXAMINER		DATE CONSIDERED				

2565997-1

RECEIVED

FEB 1 3 2003

TECH CENTER 1600/2900